

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision:10.07.2017
--------	---	--

User guide

Name of manufacturer

TOR VM Ltd.

Registered trade mark of manufacturer



Address of manufacturer

Novatorov street, 7A, 119421 Moscow, Russia
Manufacturing site:
Kulibina, 15c, 394000 Voronezh, Russia
General manager: Dr. Oleg Mikhalev
Technical and manufacturing manager: Dr. Mikhail Lesovoy
Tel.: (495) 936 74 04, (495) 225 54 17
Fax : (495) 936 12 55
e-mail: torvm@gmail.com
internet: www.torvm.ru

European representative

Gregor Kostunov
Untere Seegasse 54, DE-69124 Heidelberg, Germany
Tel/fax (49) 6221718120
E-mail: tor.vm.de@googlemail.com

The products are CE marked



Notified body

SZUTEST

Notified Body Number: 2195
Szutest Uygunluk Değerlendirme A.Ş.
Yukarı Dudullu Mh. Nato Yolu Cd. Çam Sk. No:7 Ümraniye, İstanbul, TÜRKİYE
Tel.: +90 (216) 469 46 66
Fax: +90 (216) 469 46 67
E-Posta: info@szutest.com.tr

Trade names and catalogue numbers

List of Products (see Annex 1)

TOR VM	Dental Polishing Discs and Mandrels	Date of Issue: 10.08.2016
	TECHNICAL FILE	Version: 3
	Addendum 16.1. Instruction for Use (IFU)	Date of Revision:10.07.2017

Intended purpose

TOR VM dental polishing discs are intended for professional use in dental clinic only. Polishing discs with metal connector and stem polishing discs with plastic connector (hereinafter - *discs*) can be used for all groups of patients without restrictions.

The *discs* are intended for polishing dental fillings via rotation transferred from dental handpiece manipulated by dentist or by hand manipulation of handpiece around the dent.

Mandrels are used to transfer rotation from dental handpiece to the *disc* or as intermediate (adapter, transition adapter) between *discs* and handpiece.

Discs are for single use and supplied in non sterile state. It is obvious that polishing disc has been used.

Discs are single-use devices. *Discs* are used for composite finishing and polishing. *Disc* flexibility allows the *disc* to bend, proving perfect polishing effect even in interproximal areas. The best result is achieved when *discs* of all 4 types are used successively - from the coarsest to the finest one.

Mandrels are supplied in non sterile state.

Mandrels can be re-used and must be sterilized after each procedure .

TOR VM disc instruction

1. Remove excess composite and contour the restoration using a fine diamond or carbide bur.
2. Accurately open the package with *discs* to avoid squabbling and mixing of the *discs* and choose *disc* for gross reduction of necessary diameter.
3. Place *disc* for gross reduction by gentle pushing of the connector onto preliminary sterilized mandrel until the *disc* is secure connected (*disc* must not wobble on mandrel).
4. Start polishing at a speed not more than 10000 rpm. (speed and duration when using *disc* of another type see the Table)

Process	Gross reduction	Contouring	Finishing	Polishing
Standard color code	blue	green	yellow	white
Speed, rpm	10000	10000	30000	30000
Time, seconds	As needed	15 - 20	15 - 20	15 - 20

5. When the polishing is finished wash away the residuals of polishing.
6. Remove the gross reduction *disc* from mandrel by positioning a thumbnail under the *disc* connector and pushing the *disc* away from the mandrel.
7. Place *disc* for contouring by gentle pushing of the connector onto mandrel until the *disc* is secure (*disc* must not wobble on mandrel) and repeat procedures 3 – 4 taking into account changed abrasiveness of the *disc* (see the Table).

When polishing pay attention to:

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision: 10.07.2017
--------	---	---

- a. move in one direction: from gingiva towards restoration (back and forth movement over the composite-enamel margin is not recommended);
- b. use light pressure;
- c. keep the restoration surface and *disc* dry when polishing to reach more smooth and uniform effect;
- d. cool the polished tooth with air to avoid dentin overheating.

Warning:

1. Do not use *discs* and mandrels on handpieces intended for speeds exceeding 30000 rpm to avoid the *disc* or mandrel damage that may lead to an injury.
2. Do not operate mandrel without *disc*.
3. Avoid contacting of mandrel or *disc* connector with composite - possible discoloration may require to repeat polishing once more.
4. Use successively *discs* of all 4 types - otherwise the quality of restoration polishing may be reduced.
5. Control quality of *disc* surface while operating. Rotational behavior and the appearance of the *disc* changes 10-15 seconds before separation or break. The visual appearance of the disintegrated *disc* is changed. Do not use *discs* with delaminated abrasive coating or damaged polymer part. This may cause tissue damage.
6. Control the cooling air supply during polishing to avoid dentin overheating.
7. Do not use polishing *disc* once more – *discs* are single-use device – second use can lead to:
 - tissue infection,
 - tissue damage caused by delamination of abrasive coating,
 - tissue damage by parts of disintegrated *disc*,
 - tissue damage caused by disconnection between *disc* and mandrel.
8. If package with *discs* or mandrels is broken or disrupted *discs* or mandrels prior to use must be sterilized by a standard method.

Methods of sterilization

Mandrels are sterilized after each patient using either conventional steam autoclave or dry heat sterilizer.

Warning:

1. Do not use detergents or disinfectants containing strong alkalines (pH>9), strong acids (pH<4), phenols or iodophors, hydrogen peroxide, interhalogenic agents, halogenic hydrocarbons, strong oxidizing agents, organic solvents, aldehydes.
2. Use only sterile or high quality water for post-rinsing.
3. Dry mandrels thoroughly before sterilization.
4. Do not exceed sterilization temperature of 138°C.
5. Follow instructions of autoclave (sterilizer) manufacturer.

In case of risk of disc contamination discs can be sterilized in the following manner:

- 1) put discs in 2% sodium bicarbonate solution at 70°C for 15 min, mix from time to time,
- 2) rinse with distilled water,
- 3) dry at ambient temperature,
- 4) put in 6% solution of hydrogen peroxide at ambient temperature for 360 min or at 50°C for 180 min.

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision:10.07.2017
--------	---	--

Storage

Store *discs* and mandrels in a dry place.

Store *discs* away from direct sunlight. The storage at direct light can cause disc color change and flexibility decrease.

Product shelf-life

Shelf-life of *discs* is 5 years since date of production.

Shelf-life of mandrels is unlimited.

Warranty

Warranty time for mandrels is 1 year after the first use.

Discs are single-use devices.

TOR VM will replace the product that is proved to be nonconforming.

It is up to user to ensure that the product is suitable for the intended process and purpose.

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision:10.07.2017
--------	---	--

Annex 1

List of Products

Discs abrasive part is PET film covered by aluminum oxide particles in colored polymeric binder.
Connectors of polishing discs are made of brass, connectors of stem polishing discs are made of PVC.
Mandrels are made of stainless steel 1.4034.

Catalogue number	Product name
1.111	Mandrel for stem polishing discs RA type - 1 pc.
1.110	Mandrel for stem polishing discs HP type - 1 pc.
1.115	Mandrel for stem polishing discs RA type - 1 pc.
1.600	Stem discs including: - stem polishing discs for gross reduction: 8 mm in diameter (catalogue number 1.611) - 10 pcs., 12 mm in diameter (catalogue number 1.621) - 10 pcs., 14 mm in diameter (catalogue number 1.631) - 10 pcs., - stem polishing discs for contouring: 8 mm in diameter (catalogue number 1.612) - 10 pcs., 12 mm in diameter (catalogue number 1.622) - 10 pcs., 14 mm in diameter (catalogue number 1.632) - 10 pcs., - stem polishing discs for finishing: 8 mm in diameter (catalogue number 1.613) - 10 pcs., 12 mm in diameter (catalogue number 1.623) - 10 pcs., 14 mm in diameter (catalogue number 1.633) - 10 pcs., - stem polishing discs for polishing: 8 mm in diameter (catalogue number 1.614) - 10 pcs., 12 mm in diameter (catalogue number 1.624) - 10 pcs., 14 mm in diameter (catalogue number 1.634) - 10 pcs., - stem polishing discs with back abrasive position 14 mm in diameter: for gross reduction (catalogue number 1.631o) - 10 pcs., for contouring (catalogue number 1.632o) - 10 pcs., for finishing (catalogue number 1.633o) - 10 pcs., for polishing (catalogue number 1.634o) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.610	Stem polishing discs including: - stem polishing discs 8 mm in diameter: for gross reduction (catalogue number 1.611) - 10 pcs., for contouring (catalogue number 1.612) - 10 pcs., for finishing (catalogue number 1.613) - 10 pcs., for polishing (catalogue number 1.614) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.620	Stem polishing discs including: - stem polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.621) - 10 pcs., for contouring (catalogue number 1.622) - 10 pcs., for finishing (catalogue number 1.623) - 10 pcs., for polishing (catalogue number 1.614) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision: 10.07.2017
--------	---	---

1.630	Stem polishing discs including: - stem polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.631) - 10 pcs., for contouring (catalogue number 1.632) - 10 pcs., for finishing (catalogue number 1.633) - 10 pcs., for polishing (catalogue number 1.634) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.020D	Finishing and Polishing kit including: - stem polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.631) - 12 pcs., for contouring (catalogue number 1.632) - 12 pcs., for finishing (catalogue number 1.633) - 12 pcs., for polishing (catalogue number 1.634) - 12 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.611	Stem discs for gross reduction 8 mm in diameter - 40 pcs.
1.621	Stem discs for gross reduction 12 mm in diameter - 40 pcs.
1.631	Stem discs for gross reduction 14 mm in diameter - 40 pcs.
1.612	Stem discs for contouring 8 mm in diameter - 40 pcs.
1.622	Stem discs for contouring 12 mm in diameter - 40 pcs.
1.632	Stem discs for contouring 14 mm in diameter - 40 pcs.
1.613	Stem discs for finishing 8 mm in diameter - 40 pcs.
1.623	Stem discs for finishing 12 mm in diameter - 40 pcs.
1.633	Stem discs for finishing 14 mm in diameter - 40 pcs.
1.614	Stem discs for polishing 8 mm in diameter - 40 pcs.
1.624	Stem discs for polishing 12 mm in diameter - 40 pcs.
1.634	Stem discs for polishing 14 mm in diameter - 40 pcs.
1.650	Stem polishing discs including: - stem polishing discs 8 mm in diameter: for gross reduction (catalogue number 1.651(8)) - 4 pcs., for contouring (catalogue number 1.652(8)) - 4 pcs., for finishing (catalogue number 1.653(8)) - 4 pcs., for polishing (catalogue number 1.644(8)) - 4 pcs., - stem polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.651(12)) - 4 pcs., for contouring (catalogue number 1.652(12)) - 4 pcs., for finishing (catalogue number 1.653(12)) - 4 pcs., for polishing (catalogue number 1.644(12)) - 4 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.115) - 1 pc
1.651(8)	Stem polishing discs for gross reduction 8 mm in diameter - 40 pcs.
1.651(12)	Stem polishing discs for gross reduction 12 mm in diameter - 40 pcs.
1.651(14)	Stem polishing discs for gross reduction 14 mm in diameter - 40 pcs.
1.652(8)	Stem polishing discs for contouring 8 mm in diameter - 40 pcs.
1.652(12)	Stem polishing discs for contouring 12 mm in diameter - 40 pcs.
1.652(14)	Stem polishing discs for contouring 14 mm in diameter - 40 pcs.
1.653(8)	Stem polishing discs for finishing 8 mm in diameter - 40 pcs.
1.653(12)	Stem polishing discs for finishing 12 mm in diameter - 40 pcs.
1.653(14)	Stem polishing discs for finishing 14 mm in diameter - 40 pcs.
1.654(8)	Stem polishing discs for polishing 8 mm in diameter - 40 pcs.
1.654(12)	Stem polishing discs for polishing 12 mm in diameter - 40 pcs.

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision:10.07.2017
--------	---	--

1.654(14)	Stem polishing discs for polishing 14 mm in diameter - 40 pcs.
1.611o	Stem polishing discs for gross reduction with back abrasive position 8 mm in diameter - 40 pcs.
1.621o	Stem polishing discs with back abrasive position 12 mm in diameter - 40 pcs.
1.631o	Stem polishing discs with back abrasive position 14 mm in diameter - 40 pcs.
1.612o	Stem polishing discs for contouring with back abrasive position 8 mm in diameter - 40 pcs.
1.622o	Stem polishing discs for contouring with back abrasive position 12 mm in diameter - 40 pcs.
1.632o	Stem polishing discs for contouring with back abrasive position 14 mm in diameter - 40 pcs.
1.613o	Stem polishing discs for finishing with back abrasive position 8 mm in diameter - 40 pcs.
1.623o	Stem polishing discs for finishing with back abrasive position 12 mm in diameter - 40 pcs.
1.633o	Stem polishing discs for finishing with back abrasive position 14 mm in diameter - 40 pcs.
1.614o	Stem polishing discs for polishing with back abrasive position 8 mm in diameter - 40 pcs.
1.624o	Stem polishing discs for polishing with back abrasive position 12 mm in diameter - 40 pcs.
1.634o	Stem polishing discs for polishing with back abrasive position 14 mm in diameter - 40 pcs.
1.651(8)o	Stem polishing discs for gross reduction with back abrasive position 8 mm in diameter - 40 pcs.
1.651(12)o	Stem polishing discs for gross reduction with back abrasive position 12 mm in diameter - 40 pcs.
1.651(14)o	Stem polishing discs for gross reduction with back abrasive position 14 mm in diameter - 40 pcs.
1.652(8)o	Stem polishing discs for contouring with back abrasive position 8 mm in diameter - 40 pcs.
1.652(12)o	Stem polishing discs for contouring with back abrasive position 12 mm in diameter - 40 pcs.
1.652(14)o	Stem polishing discs for contouring with back abrasive position 14 mm in diameter - 40 pcs.
1.653(8)o	Stem polishing discs for finishing with back abrasive position 8 mm in diameter - 40 pcs.
1.653(12)o	Stem polishing discs for finishing with back abrasive position 12 mm in diameter - 40 pcs.
1.653(14)o	Stem polishing discs for finishing with back abrasive position 14 mm in diameter - 40 pcs.
1.654(8)o	Stem polishing discs for polishing with back abrasive position 8 mm in diameter - 40 pcs.
1.654(12)o	Stem polishing discs for polishing with back abrasive position 12 mm in diameter - 40 pcs.
1.654(14)o	Stem polishing discs for polishing with back abrasive position 14 mm in diameter - 40 pcs.
1.021D	Finishing and Polishing kit including: - polishing discs 14 mm in diameter:

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision: 10.07.2017
--------	---	---

	for gross reduction (catalogue number 1.731(14)) - 12 pcs., for contouring (catalogue number 1.732(14)) - 12 pcs., for finishing (catalogue number 1.733(14)) - 12 pcs., for polishing (catalogue number 1.734(14)) - 12 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.075	Polishing discs including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 10 pcs., for contouring (catalogue number 1.732(14)) - 10 pcs., for finishing (catalogue number 1.733(14)) - 10 pcs., for polishing (catalogue number 1.734(14)) - 10 pcs., - polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.731(12)) - 10 pcs., for contouring (catalogue number 1.732(12)) - 10 pcs., for finishing (catalogue number 1.733(12)) - 10 pcs., for polishing (catalogue number 1.734(12)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.076	Polishing discs including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 30 pcs., for contouring (catalogue number 1.732(14)) - 30 pcs., for finishing (catalogue number 1.733(14)) - 30 pcs., for polishing (catalogue number 1.734(14)) - 30 pcs., - polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.731(12)) - 30 pcs., for contouring (catalogue number 1.732(12)) - 30 pcs., for finishing (catalogue number 1.733(12)) - 30 pcs., for polishing (catalogue number 1.734(12)) - 30 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.077	Polishing discs including: - polishing discs 9,3 mm in diameter: for gross reduction (catalogue number 1.731(A)) - 30 pcs., for contouring (catalogue number 1.732(A)) - 30 pcs., for finishing (catalogue number 1.733(A)) - 30 pcs., for polishing (catalogue number 1.734(A)) - 30 pcs., - polishing discs 12,7 mm in diameter: for gross reduction (catalogue number 1.731(B)) - 30 pcs., for contouring (catalogue number 1.732(B)) - 30 pcs., for finishing (catalogue number 1.733(B)) - 30 pcs., for polishing (catalogue number 1.734(B)) - 30 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.069	Polishing discs including: - polishing discs 10 mm in diameter: for gross reduction (catalogue number 1.731(10)) - 10 pcs., for contouring (catalogue number 1.732(10)) - 10 pcs., for finishing (catalogue number 1.733(10)) - 10 pcs., for polishing (catalogue number 1.734(10)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.070	Polishing discs including: - polishing discs 12 mm in diameter:

TOR VM	Dental Polishing Discs and Mandrels TECHNICAL FILE Addendum 16.1. Instruction for Use (IFU)	Date of Issue: 10.08.2016 Version: 3 Date of Revision: 10.07.2017
--------	---	---

	for gross reduction (catalogue number 1.731(12)) - 10 pcs., for contouring (catalogue number 1.732(12)) - 10 pcs., for finishing (catalogue number 1.733(12)) - 10 pcs., for polishing (catalogue number 1.734(12)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.071	Polishing discs including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 10 pcs., for contouring (catalogue number 1.732(14)) - 10 pcs., for finishing (catalogue number 1.733(14)) - 10 pcs., for polishing (catalogue number 1.734(14)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.072	Polishing discs including: - polishing discs 16 mm in diameter: for gross reduction (catalogue number 1.731(16)) - 10 pcs., for contouring (catalogue number 1.732(16)) - 10 pcs., for finishing (catalogue number 1.733(16)) - 10 pcs., for polishing (catalogue number 1.734(16)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.731(A)	Polishing discs for gross reduction 9,3 mm in diameter - 50 pcs.
1.731(10)	Polishing discs for gross reduction 10 mm in diameter - 40 pcs.
1.731(12)	Polishing discs for gross reduction 12 mm in diameter - 40 pcs.
1.731(B)	Polishing discs for gross reduction 12,7 mm in diameter - 50 pcs.
1.731(14)	Polishing discs for gross reduction 14 mm in diameter - 40 pcs.
1.731(16)	Polishing discs for gross reduction 16 mm in diameter - 40 pcs.
1.732(A)	Polishing discs for contouring 9,3 mm in diameter - 50 pcs.
1.732(10)	Polishing discs for contouring 10 mm in diameter - 40 pcs.
1.732(12)	Polishing discs for contouring 12 mm in diameter - 40 pcs.
1.732(B)	Polishing discs for contouring 12,7 mm in diameter - 50 pcs.
1.732(14)	Polishing discs for contouring 14 mm in diameter - 40 pcs.
1.732(16)	Polishing discs for contouring 16 mm in diameter - 40 pcs.
1.733(A)	Polishing discs for finishing 9,3 mm in diameter - 50 pcs.
1.733(10)	Polishing discs for finishing 10 mm in diameter - 40 pcs.
1.733(12)	Polishing discs for finishing 12 mm in diameter - 40 pcs.
1.733(B)	Polishing discs for finishing 12,7 mm in diameter - 50 pcs.
1.733(14)	Polishing discs for finishing 14 mm in diameter - 40 pcs.
1.733(16)	Polishing discs for finishing 16 mm in diameter - 40 pcs.
1.734(A)	Polishing discs for polishing 9,3 mm in diameter - 50 pcs.
1.734(10)	Polishing discs for polishing 10 mm in diameter - 40 pcs.
1.734(12)	Polishing discs for polishing 12 mm in diameter - 40 pcs.
1.734(B)	Polishing discs for polishing 12,7 mm in diameter - 50 pcs.
1.734(14)	Polishing discs for polishing 14 mm in diameter - 40 pcs.
1.734(16)	Polishing discs for polishing 16 mm in diameter - 40 pcs.
1.120	Mandrel of HP type for polishing discs - 1 pc.
1.121	Mandrel of RA type for polishing discs - 1 pc.