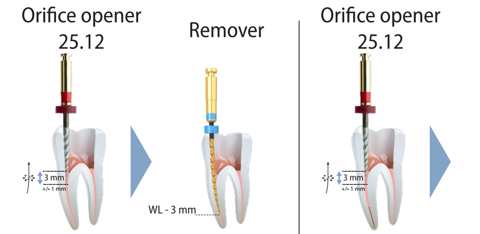
HyFlex Remover NiTi Root Canal Instruments

HyFlex Remover Protocol



1= Complete obturation

2= Incomplete obturation

	Ø	%	L	Stop	Ring	RPM	Recommended torque (N.cm)
Orifice Opener 25.12	25	12	15	● (red)	● (red)	400	2.5
Remover	30	7	19 23	● (blue)	● (blue)	400 800	2.5

Instruction for use EN

1. **Indication**

Remover: Gutta-Percha desobturation/removal during non-surgical endodontic retreatment which occurs after endodontic treatment.

Only to be used by dental professionals.

2. **Contraindications**

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there are no contraindications to the use of Remover for endodontically treating a tooth by orthograde route.

3. **Complications**

In cases of complex anatomies and/or depending on obturation materials, per-operative risks (instrumental breakage, ledge, stripping, zipping, false path, perforation…) could occur and induce a risk of infectious processes.

4. **Warnings and precautions**

- The decision to use an endodontic instrument must correspond to clinical expertise, particularly if the root canal anatomy is overly complex.
- Patients identified as having a risk of infectious endocarditis.
- Contains nickel and titanium and should not be used on patient with known allergic sensitivity to these metals.
- Follow the good dental practice, in particular the use of a dental dam and gloves.
- Use in continuous rotation at the recommended speed.
- In cases of complex anatomies, the maximum torque can differ from the recommended value by the manufacturer.
- Use according to the procedure recommended (§7).
- Do not use except for the desobturation/removal of Gutta-Percha.
- Instruments supplied non-sterile: Follow the reprocessing instructions (§8) before use.
- Instruments supplied sterile: Check the integrity of the packaging before use. If damaged, do not use the instrument.
- If applicable, respect the expiry date.
- Year of manufacturing: see labelling.
- Do not use if in doubt about compliance with storage conditions.
- Instrument single use: Do not re-use the instrument. Otherwise the risk is a decrease of performances and security characteristics (fracture of the instrument in the tooth).
- In case of doubt concerning the product identification, do not use.
- Check the instrument state before the use between each canal. If the instrument is damaged or shows signs of wear, do not use the instrument.
- Inform the manufacturer and the country regulatory authority of any serious incident related to the instrument.

Packaging symbol	STERILE EO	(2)	Sterile ethylene oxide, Do not re-use
Packaging symbol	NON STERILE	(2)	Not sterile Do not re-use

5. **Clinical claims**

Remover in normal conditions.

Clinical performance :

- Desobturation/removal ability: debris removal and removal efficiency adapted.
- Limits the use of solvent.
- Respect of canal anatomy: the instrument is centered in the canal.
- Geometry adapted to irrigation: Geometry of 7% is adapted to irrigation due to the protocol (WL – 3 mm).
- The apical foramen is maintained due to the protocol (WL-3mm).

Usability :

- Easy to use: 1 instrument.
- Pre-bendable: better access to the canal.
- Improved flexibility due to heat treatment.

Safety :

- Limited risk of breakage
- Limited per-operative risks
- No cross-contamination risk

6. **Characteristics**

Type 2 rotary instruments according to EN ISO 3630-1: 2019:

- Maximum recommended torque (not required): see table "Recommended Torque".

Material of operative part: Nitinol.

Use in connection with an endodontic contra-angle according to EN ISO 1797: 2017 (Type 1).

Number of uses: Single use, 3 canals maximum recommended on the same patient.

Medical device class according to 93/42 directive and MDR 2017/745: IIa.

7. **Protocol**

Use only for Gutta-Percha obturation.
Operating procedure:

The instruments must be used with a back and forth motion without any apical pressure up to the working length – 3 mm (WL) if there is a complete obturation or until the first obturation. It is possible to use a brushing motion.

Remove and clean the instrument and irrigate the canal when apical resistance or a slight apical pull is encountered.

Note: It is necessary to irrigate abundantly between each instrument passage and to clean the turns of the instrument after each insertion into the canal. Check the instrument between every canal (see §4).

8. **Reprocessing instructions**

General recommendations	• For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents. • For your own safety, please wear personal protective equipment (gloves, glasses and mask). • Do not use cleaning or disinfecting agents containing phenol, aldehyde and alkaline composition. • Always follow the instructions for use provided by the manufacturer of the products. • Symbol: (2) Do not re-use; STERILE EO Sterilized using ethylene oxide
Limitations on reprocessing	• Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. Multiple use disinfection and re-sterilization cycles may lead to increased risk of file separation. • The user must ensure that the processing method used, including resources, materials and personnel, is appropriate and meets the applicable requirements. • State of the art and national laws require that validated procedures be followed.
Material needed	• Gloves, masks, gown as recommended by the manufacturer of the cleaner and detergent • Running or deionized water • Disinfectant (neodisher® Septo Active) • Detergent (neodisher® MediZym) • Small soft brushes • Container • Ultrasonic bath or washer-disinfector • Class B sterilization apparatus *Remark: All materials used should be cleaned and replaced regularly. Identify material used for each step of the process (initial treatment, cleaning or rinsing).*

	1	**Initial Treatment** Place used products in a container or a wipe with tap water at 20-40 °C and 1.0 % neodisher® Septo Active for between 5 and 15min. Rinse the products with tap water at 20-40 °C for 1 min. If there is a pause before next step, make sure the device stays moist by packing it in a wet wipe. Do not exceed 1 hour waiting time. *Remarks: • Do not use fixating agents or hot water (> 40 °C), as this causes fixation of residues and can impair successful cleaning. • Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects of the devices).*
	2	**Preparation Before Cleaning** If the devices have visible impurities, it is recommended to manually pre-clean by brushing under tap water at 20-40°C at least 1min with a soft brush until the disappearance of impurities. *Remark: Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects of the devices).*
	3	**Visual Inspection** Inspect the used products and discard the damaged products (broken, untwisted or abnormally bent)
manual	4	**Cleaning** Insert the products in the ultrasonic bath. Run ultrasonic device for 10-30min with tap water and 0.5-2.0% neodisher® MediZym *Remarks: Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution.*
manual	5	**Rinsing** Rinse the products with tap water at 20-40°C for 1min. *Remark: It is recommended to use deionized water.*
manual	6	**Drying** Dry the products with compressed air until product is visibly dry.
automatic	4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray of the slide-in trolley of the washer/disinfector. Perform cleaning cycle with 0.2-1.0% neodisher® MediZym. Perform drying. *Remarks: • Disinfection (thermal or chemico-thermal) is not required as the products are sterilized after cleaning. • Follow instructions and concentrations given by the manufacturer of the detergent solution. • Follow the instructions of the washer-disinfector and check that the success criteria after each cycle have been met as stated by the manufacturer. • The final rinsing step should be performed with deionized water. For other steps follow the water quality defined by the manufacturer. • Use only approved washer-disinfectors according to EN ISO 15883, which are maintained and validated regularly.*
	7	**Visual Inspection** Inspect the used products. Repeat steps 4-5-6 if the product is not clean visibly or discard the damaged products.
	8	**Packaging** Place the instruments in a paper-plastic pouch for steam sterilization compliant with ISO 11607 and EN 868. *Remarks: • For sharp devices that are not contained within a box, silicone tubes should be placed around the devices to prevent piercing the packaging. • Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermo-sealer must be calibrated and qualified.*
	9	**Sterilization** Sterilize the products with steam vapor • Apparatus: class B • Minimum temperature: 132°C • Minimum time: 3min • Absolute pressure: 2.2 bar • Minimum drying: 20min Control the physico-chemical indicators and cycle parameters. *Remarks: • The settings temperature at 134 °C and duration of 18 min are recommended for prion inactivation according to French regulations. • When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded. • Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer. • Use only pre-vacuum air removal steam sterilizers that meet the requirements of EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer), with saturated steam.*
	10	**Storage** Store the products in a dry, clean and dust-free environment at temperatures specified for paper-plastic pouch by steam sterilization manufacturer. *Remark: Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date). In case of damage, a complete rework should be performed.*

9. **Storage and transport conditions**

Store sterile instruments in their original packaging, protected from sunlight and heat, in a clean and dry place.

10. **Disposal**

After use, instruments must be placed in a secure container, used to collect cutting or piercing instruments (like needles or disposable blade) as per good dentistry practices.

11. **Symbols**

CLASSICS	"CLASSICS" handle
(package symbol)	Do not use if packaged is damaged

CE marking year: 2019

Instruction d'utilisation FR

1. **Indication**

Remover : Désobturation à base de Gutta Percha durant un retraitement endodontique non chirurgical qui intervient après le traitement endodontique.

Utilisation par un professionnel dentaire uniquement.

2. **Contre-indication**

En dehors des enfants âgés de moins de 2 ans (oxyde d'éthylène utilisé dans le processus de stérilisation), il n'existe aucune contre-indication à l'utilisation de Remover pour traiter endodontiquement une dent par voie orthograde.

3. **Effets indésirables/ Complications**

Dans les cas d'anatomies complexes et/ou en fonction du matériau d'obturation, un risque per-opératoire (rupture, ovalisation, zipping, stripping, butée) pourrait se produire et induire un risque de processus infectieux.

4. **Mise en garde/Précautions**

- La décision d'utiliser l'instrument endodontique doit être relayée à l'expertise du cas clinique en particulier pour une anatomie canalaire jugée trop complexe.
- Patients identifiés comme possédant un risque d'endocardite infectieuse.
- Contient du nickel et du titane : ne doit pas être utilisé chez les personnes présentant une allergie connue à ces métaux.
- Respecter les bonnes pratiques dentaires en particulier l'utilisation d'une digue dentaire et des gants.
- Utiliser en rotation continue à la vitesse préconisée.
- Dans les cas d'anatomie complexe, le couple d'utilisation maximum peut être différent de la valeur recommandée par le fabricant.
- Utiliser conformément à la technique recommandée (§7).

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7. **Protokoll**

Kizárólag guttapercha obturációhoz használja.

Műtéti eljárás:
Az eszközt a használatához előre-hátra kell mozgatni, apikális nyomás kifejtése nélkül a munka hosszában – 3 mm (WL) teljes obturáció esetén vagy az első obturációig. Lehetséges sikáló mozgás végzése.

Ha apikálisan ellenállás észlelhető, vagy enyhe apikális nyomás tapasztalható, távolítsa el és tisztítsa meg az eszközt, és öblítse át a csatornát.

Megjegyzés: minden újabb eszközbehatolás előtt bőséges öblítést kell végezni, és az eszköznek a gyökércsatornába való minden újabb bevezetése után meg kell tisztítani a hornyokat. Ellenőrizze az eszközt a különböző gyökércsatornákban történő használatok között (lásd: 4. pont).

3	**Vizuális ellenőrzés** Vizsgálja meg a használt eszközöket, és dobja ki azokat, amelyek sérültek (töröttek, rendellenesen kiegyenesedettek, illetve meghajlottak)
4	**Tisztítás** Helyezze az eszközt az ultrahangos kádba. Üzemeltesse az ultrahangos berendezést 10–30 percig 0,5–2,0% neodisher® MediZym detergenst tartalmazó csapvízzel *Megjegyzések: kövesse az utasításokat, és tartsa be a tisztítószer gyártója által megadott vízminőséget, koncentrációkat és tisztítási időt.*

10	*Megjegyzés: használat előtt ellenőrizze a csomagolást és az orvostechnikai eszközöket (a csomagolás sértetlenségét, a páramentességet és a lejárati időt). Sérülés esetén a teljes folyamatot újra el kell végezni.*

9. **Tárolási és szállítási körülmények**
A steril eszközöket az eredeti csomagolásukban, napfénytől és hőtől védve, tiszta és száraz helyen tárolja.

10. **Ártalmatlanítás**
Használat után az eszközöket olyan biztonságos tartályba kell helyezni, amely alkalmas éles és hegyes eszközöknek (pl. tűk vagy eldobható szikék) a helyes fogászati gyakorlatnak megfelelő gyűjtésére.

- Joustavampi lämpökäsittelyn ansiosta.

Turvallisuus:

- Vähäinen katkeamisriski
- Vähäiset toimenpiteeseen liittyvät riskit
- Ei ristikontaminaatioriskiä

6. **Ominaisuudet**
Standardin EN ISO 3630-1: 2019 tyypin 2 mukainen pyörivä instrumentti:

- Suositeltu enimmäisvääntömomentti (ei välttämätön): Katso taulukko "Recommended torque".

Toimenpideosan materiaali: nitinoli.

Käyttö yhdessä standardin EN ISO 1797: 2017 (tyyppi 1) mukaisen juurihoitoon tarkoitetun kulmakappaleen kanssa.

2	**Valmistelu ennen puhdistusta** Jos instrumenteissa on näkyviä epäpuhtauksia, suositellaan manuaalista esipuhdistusta harjaamalla instrumentteja pehmeällä harjalla vesijohdovedessä 20–40 °C:n lämpötilassa vähintään 1 minuutin ajan, kunnes epäpuhtauksia ei enää ole näkyvissä. *Huomautus: noudata valmistajan antamia ohjeita sekä pitoisuutta ja upotusaikaa koskevia tietoja (liian suuri pitoisuus saattaa aiheuttaa instrumenteissa syöpymiä tai muita vaurioita).*
3	**Silmämääräinen tarkastus** Tarkista käytetyt instrumentit ja hävitä vaurioituneet instrumentit

10	**Säilytys** Säilytä instrumentteja kuivassa, pölyttömässä ympäristössä ...

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