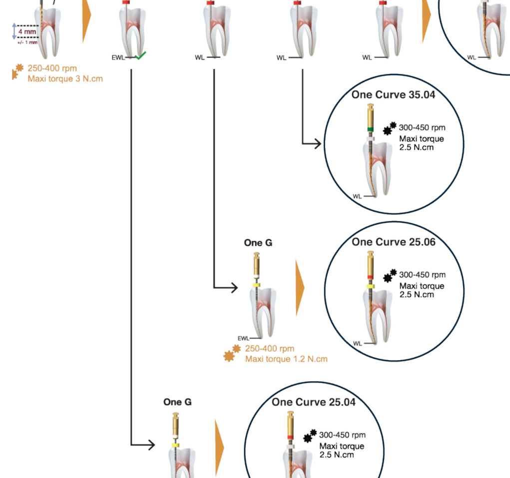
One Curve / One Curve Procedure Pack / One Curve Starter Pack NiTi Root Canal Instruments

One Curve Protocol

The Endo DNA*



	Ø	%	L	Stop	Ring	RPM	Recommended torque (N.cm)
One Flare	25	9	17	-	-	250-400	3
One G	14	3	21-25-29	● (yellow)	○	250-400	1.2
One Curve n25 4%	25	4	21-25-31	○	● (red)	300-450	2.5
One Curve n25 6%	25	6		● (yellow)	● (red)		
One Curve n35 4%	35	4		○	● (green)		
One Curve n45 4%	45	4		○	○		

Instruction for Use — EN

1. **Indication**

One Flare: flaring during non-surgical endodontics treatment.
One Curve: shaping of root canal during non-surgical endodontics treatment.
One G, K files: glide path of root canals during non-surgical endodontic treatment.
Use by a dental professional only.

2. **Contraindications**

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there is no contraindication to the use of One Curve for endodontically treating a tooth by orthograde.

3. **Complications**

In cases of complex anatomy, per-operative risks (instrumental breakage, ledge, stripping, zipping, false path, perforation…) could occur and induce a risk of infectious processes.

4. **Warning and precautions**

- The decision to use an endodontics instrument must be relayed to the clinical case expertise in particular for a canal anatomy considered as too complex.
- Patients identified as having a risk of infectious endocarditis.
- Contains Nickel and Titanium and should not be used for patient with known allergic sensitivity to these metals.
- Respect the good dental practice in particular the use of dental dam and gloves.
- Use in continuous rotation at the recommended speed.
- In cases of complex anatomy, the maximum torque can be different than the recommended value by the manufacturer.
- Use according to the procedure recommended (§7).
- Do not use in retreatment.
- Instruments supplied non-sterile: Follow the reprocessing instruction (§8) before use.
- Instruments supplied sterile: Check the integrity of the package before use. If damaged, do not use the instrument
- If applicable, respect the expiry date.
- Year of manufacturing: see labelling.
- Do not use if doubt on the respect of storage conditions.
- Instrument single use: Do not reuse 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.

209XXXXX	STERILE EO	(Do not re-use)
201XXXXX	NON STERILE	(Do not re-use)

5. **Clinical claims**

One Curve in normal conditions.
Clinical performance:

- Shaping ability: debris removal and cutting efficiency adapted
- Respect of canal anatomy
- Geometry adapted to irrigation
- Maintain of the apical foramen in its original position

Usability :

- Easy to use: 1 instrument
- Pré-curvable: better access to the canal
- Improved flexibility thanks to heat treatment

Safety :

- Limited risk of breakage
- Limited risk of aberrations
- No cross-contamination risk

Note: K Files and One G are glide path files used before shaping operation. One Flare is a flaring instrument occurring in the beginning of the shaping.

6. **Characteristics**

K Files:

- Diameters 10 (purple handle), 15 (white handle), 20 (yellow handle), 25 (red handle)
- Taper .02 (red stop)
- Material of operative part: Stainless steel
- Lengths: 21 – 25 – 29 mm

Type 2 rotating instruments of 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, 5 maximum canals recommended on a same patient.
Medical device class according to 93/42 Directive: IIa.

7. **Protocol**

Operating procedure:
The instruments must be used with a back and forth motion without any apical pressure.
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 introduction into the channel. Verify the instrument between every canals (see §4).

8. **Reprocessing instruction (only for non sterile products)**

General recommandations		• 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 respect the instruction for use provided by the manufacturer of the products. • Symbols: (symbol) 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. • The state of the art and national laws require that validated procedures be followed.
Material needed		Gloves, masks, blouse as recommended by the manufacturer of cleaner and detergent • Tap or deionized water • Disinfectant (neodisher® Septo Active) • Detergent (neodisher® MediZym) • Small soft brushes • Container • Ultrasonic tub or washer-disinfector • Class B sterilization apparatus *Remark: All material 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 during between 5 and 15min. Rinse the products with tap water at 20-40 °C during 1 min. If there is waiting time 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 on 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 on 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 ultrasound apparatus beaker Run ultrasound apparatus during 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 during 1min. *Remark: It is recommended to use deionized water.*
manual	6	**Drying** Dry the products with compressed air until product visibly dried.
automatic	4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray of the on the slide-in trolley of the washer/disinfector. Perform cleaning cycle with 0,2-1,0% neodisher® MediZym. Perform drying. *Remarks*: • *Disinfection (thermal or chemical-thermal) is not required since the products are sterilized after the cleaning.* • *Follow instructions and concentrations given by the manufacturer of the detergent solution.* • *Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer.* • *The final rinse step should be with deionized water. For other steps follow the water quality defined by the manufacturer.* • *Use only approved washer-disinfector according to EN ISO 15883, maintained and validated regularly.*
	7	**Visual Inspection** Inspect the used products. Re-do steps 4-5-6 if the product visibly not clean or discard the damaged products.
	8	**Packaging** Place the instruments in a paper-plastic pouch for steam sterilization compliant to ISO 11607 and EN 868. *Remarks*: • *For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.* • *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 physi-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 regulation.* • *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 sterilizer that are matching 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 temperature specified by paper-plastic pouch for 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 condition**

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 sticking instruments (like needles or disposable bistoury) as per good dentistry practices.

11. **Symbols**

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

CE marking year: 2019

Instruction d'utilisation — FR

1. **Indication**

One Flare : Evasement coronaire durant un traitement endodontique non chirurgical.
One Curve : mise en forme initiale des canaux radiculaires durant un traitement endodontique non chirurgical.
One G, K Files : cathétérisme des canaux radiculaires durant un traitement endodontique non chirurgical.
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 One Curve pour traiter endodontiquement une dent par voie orthograde.

3. **Effets indésirables/ Complications**

Dans les cas d'anatomie canalaires complexes, 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).
- Ne pas utiliser en retraitement.
- Instrument fourni non stérile : Suivre la procédure de reprocessing (§8) avant utilisation.
- Instrument fourni stérile : Vérifier l'intégrité de l'emballage avant utilisation. Si endommagé, ne pas utiliser l'instrument.
- Si applicable, respecter la date de péremption.
- Année de fabrication : voir étiquetage.
- Ne pas utiliser l'instrument si doute sur le respect des conditions de stockage.
- Usage unique : ne pas réutiliser l'instrument. Sinon le risque est une diminution des caractéristiques de performances et de sécurité (fracture de l'instrument dans la dent).
- En cas de doute concernant l'identification du produit, ne pas l'utiliser.
- Vérifier l'état de la lame de l'instrument avant utilisation entre chaque canal. Si l'instrument est endommagé ou présente des signes d'usures, ne pas utiliser.
- Informer le fabricant et l'autorité réglementaire du pays de tout incident grave en lien avec l'instrument.

209XXXXX	STERILE EO	(Ne pas réutiliser)
201XXXXX	NON STERILE	(Ne pas réutiliser)

5. **Revendications cliniques**

One Curve dans les conditions normales d'utilisation.
Performance clinique :

- Faisabilité de la mise en forme : remontée des débris et efficacité de coupe adaptées
- Respect de l'anatomie du canal
- Géométrie adaptée à l'irrigation
- Maintien du foramen apical dans sa position originale

Aptitude à l'utilisation :

- Simple d'utilisation : 1 seul instrument
- Pré-courbable : meilleur accès au canal
- Amélioration de la flexibilité grâce au traitement thermique

Sécurité :

- Risque de fracture limité
- Risque per-opératoire limité
- Pas de risque de contamination croisée

Note : K Files et One G sont des instruments de cathétérisme utilisés avant l'opération de mise en forme. One Flare est un instrument d'évasement coronaire intervenant au début de la mise en forme.

6. **Caractéristiques**

K Files:

- Diamètre 10 (manche violet), 15 (manche blanc), 20 (manche jaune), 25 (manche rouge)
- Conicité : 2% (rondelle rouge)
- Matériaux de la partie opérative : Acier inoxydable
- Longueurs : 21 – 25 – 29 mm

Instruments rotatifs de type 2 de la norme EN ISO 3630-1 : 2019 :

- Couple recommandé maximum (non obligatoire) : voir tableau « Recommended Torque »

Matériaux de la partie opérative : Nickel-Titane.
Utilisation en connexion avec un contre-angle endodontique conforme à la norme EN ISO 1797 :2017 (type 1).
Nombre de réutilisation : usage unique, 5 canaux maximum recommandés sur un même patient.
Classe médicale directive 93/42/CEE : IIa.

7. **Protocole**

Dynamique opératoire :
Les instruments doivent être utilisés en un mouvement de va-et-vient sans pression apicale.
En cas de résistance ou de légère aspiration, retirer et nettoyer les spires de l'instrument, puis irriguer le canal.
Note : Il est nécessaire d'irriguer abondamment entre chaque passage d'instrument et de nettoyer les spires de l'instrument après chaque introduction dans le canal. Vérifier l'instrument entre chaque canal (voir §4).

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Ograniczenia przygotowania do ponownego użycia		• Z uwagi na konstrukcję wyrobów i zastosowane w nich materiały nie można określić ostatecznej, maksymalnie możliwej liczby cykli przygotowania do ponownego użycia. Okres użytkowania wyrobów medycznych zależy od ich funkcji oraz od zachowania ostrożności podczas obsługi. Wielokrotne zastosowanie cykli dezynfekcji i ponownej sterylizacji może prowadzić do zwiększonego ryzyka rozdzielenia pilników. • Użytkownik musi zapewnić, że zastosowana metoda przygotowania do użycia, w tym zasoby, materiały i personel, jest odpowiednia i spełnia obowiązujące wymogi. • Aktualny stan wiedzy i przepisy krajowe wymagają przestrzegania zatwierdzonych procedur.
automatyczne	4 5 6	**Czyszczenie/płukanie/suszenie** Umieścić instrumenty na tacy wózka wsuwanego myjni-dezynfektora. Uruchomić cykl czyszczenia przy użyciu 0,2–1,0% środka neodisher® MediZym. Przeprowadzić suszenie. *Wskazówki:* • *Dezynfekcja (termiczna lub chemiczno-termiczna) nie jest wymagana, ponieważ produkty są sterylizowane po czyszczeniu.* • *Należy postępować zgodnie z instrukcjami i przestrzegać stężenia podanego przez producenta roztworu detergentu.* • *Postępować zgodnie z instrukcjami myjni-dezynfektora i sprawdzać po każdym cyklu, czy kryteria powodzenia zostały spełnione zgodnie z informacją producenta.* • *Końcowy etap płukania należy wykonać przy użyciu wody dejonizowanej. W przypadku innych etapów należy przestrzegać jakości wody określonej przez producenta.* • *Stosować wyłącznie myjnie-dezynfektory zatwierdzone zgodnie z normą EN ISO 15883, [...]*

One Curve: modelarea canalului radicular în timpul tratamentului endodontic nechirurgical.
One G, K Files: calea de alunecare a canalelor radiculare în timpul tratamentului endodontic nechirurgical.
A se utiliza numai de profesioniștii din domeniul stomatologiei.

2. **Contraindicații**
Cu excepția copiilor cu vârsta sub 2 ani (oxidul de etilenă utilizat în procesul de sterilizare), nu există nicio contraindicație pentru utilizarea produsului One Curve pentru tratarea endodontică a unui dinte prin tratament endodontic ortograd.

3. **Complicații**
În cazurile cu anatomie complexă, riscurile perioperatorii (fracturarea instrumentelor, devierea, perforarea laterală, lărgirea excesivă în zona apicală, calea falsă, perforarea...) pot apărea și pot induce un risc de procese infecțioase.

4. **Avertisment și precauții**
• Decizia de a utiliza un instrument endodontic trebuie să se bazeze pe expertiza cazuistică clinică, mai ales în situația unui canal cu o anatomie considerată ca fiind prea complexă.
• Pacienții identificați ca prezentând un risc de endocardită infecțioasă.

8. **Instrucțiuni de reprocesare**

Recomandări generale	• Pentru toate dispozitivele metalice, se recomandă să se utilizeze agenți anticorozivi de dezinfectare și de curățare. • Pentru siguranța dvs., vă rugăm să purtați echipament individual de protecție (mănuși, ochelari și mască). • Nu utilizați agenți de curățare sau de dezinfectare care au în compoziția lor fenol, aldehidă și substanțe alcaline. • Respectați întotdeauna instrucțiunile de utilizare furnizate de fabricantul produselor. • Simbol:

②	Nu reutilizați
STERILE EO	Sterilizat cu oxid de etilenă

manual	4	**Curățarea** Introduceți produsele în paharul aparatului cu ultrasunete Operați aparatul cu ultrasunete timp de 10-30 min. cu apă de la robinet și neodisher® MediZym 0,5-2,0 % *Observații: urmați instrucțiunile, respectați calitatea apei, concentrațiile și timpul de curățare indicate de producătorul soluției de curățare.*
	5	**Clătirea** Clătiți produsele cu apă de la robinet la 20-40 °C timp de 1 min. *Observație: Se recomandă utilizarea apei deionizate.*
	6	**Uscarea** Uscați produsele cu aer comprimat, până când produsul este vizibil uscat

10. **Eliminarea**
După utilizare, instrumentele trebuie așezate într-un recipient securizat, utilizat pentru colectarea instrumentelor tăioase sau aderente (cum sunt acele sau bisturiele de unică folosință), conform bunelor practici stomatologice.

11. **Simbol**

CLASSICS	Mâner „CLASSICS"
	A nu se utiliza dacă ambalajul este deteriorat

Anul marcajului CE: 2019

Návod na použitie SK

1. **Indikácia**
One Flare: rozšírenie vstupu do kanálika počas nechirurgickej endodontickej liečby.
One Curve: preparácia koreňového kanálika počas nechirurgickej endodontickej liečby.

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