# Percutaneous Dilatational Tracheostomy

# PRODUCT CATALOG



**Primed**<sup>®</sup> Medizintechnik GmbH is a highly experienced manufacturer of medical devices in the field of tracheostomy and laryngectomy.

For many years we have been supplying our customers with high quality products "MADE IN GERMANY".

According to our corporate philosophy, the **Primed**<sup>®</sup> range of medical products is developed, manufactured and distributed exclusively in our company. This is done in close cooperation with our customers as well as scientific institutions.

On the basis of a certified development process according to DIN EN 13485, highly innovative medical products are developed as a result of continuous market monitoring and analysis.

Our production covers the entire manufacturing process (injection moulding/ extrusion/ assembly), up to sterilization in our own EO sterilization facility.

The merging of all product relevant processes in one company enables us to react in an extremely flexible way to market requirements. Thus we can ensure the continuous development of our products and can also place new products on the market.

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PERCUTRACH<sup>®</sup> PDT SETS

## PDT SETS

### (PERCUTANEOUS DILATATIONAL TRACHEOSTOMY SETS)

### WITH OPTIMA PERCUTRACH®

Percutaneous dilatational tracheostomy is a standardized method in intensive medical treatment. As alternative for surgical tracheostomy it may be carried out less time-consuming at the bedside in ICU's.

The dilated tracheostoma closes spontaneously and long-term cosmetic results are far superior to conventional tracheostomy.

All **Primed**<sup>®</sup> PDT sets include a dilation set and a matching tracheostomy tube set (Optima PercuTrach<sup>®</sup>).

PDT set type 1 includes a dilation set for the Ciaglia dilation technique and an Optima PercuTrach<sup>®</sup> tracheostomy tube with atraumatic inserter.

PDT set type 2 includes a dilation set for the Griggs dilation technique, with tracheal dilating forceps, and an Optima PercuTrach<sup>®</sup> tracheostomy tube with atraumatic inserter.

Our dilation sets are ideally adapted to the use of Optima PercuTrach<sup>®</sup> tracheostomy tubes which are available with or without phonation window and with or without subglottic suction line.



### PDT SET TYPE 1



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# DILATATION TRACHEOSTOMY DEVELOPED BY CIAGLIA

The percutaneous dilatation tracheostomy technique according to Ciaglia is a minimalinvasive treatment which implies the stepless bouginage of the trachea by a conically shaped dilator via guide wire, thus enabling the insertion of a suitable tracheostomy tube.

**Primed**<sup>•</sup> **PDT Set Type 1** includes a conically shaped dilator which has a hydrophilic coating for assuring good gliding capabilities. After removing the dilator, the tracheostomy tube can be gently placed in the trachea via the atraumatic inserter.

The procedure is performed under bronchoscopic control.



Position patient with hyperextension of neck, cover area around the neck with sterile dressing, disinfect skin



Palpation of neck, sonography (recommended), diaphanoscopy of neck area (obligatory), horizontal incision(1,5-2,0 cm) and blunt preparation up to trachea



Puncture of trachea





Insertion of guide wire (Seldinger wire)

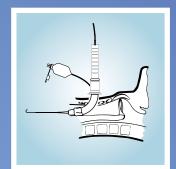


Pre-dilation of injection canal by pre-dilator, removing of pre-dilator



Moisten dilator.

Push dilator with inserted guiding catheter into the trachea via guide wire up to the required size of tracheal orifice. After that, remove dilator and guiding catheter simultaneously.



Moisten tip of atraumatic inserter with lubricant and insert in tracheal orifice via guide wire together with tested tracheostomy tube.

Remove atraumatic inserter and guide wire simultaneously.





#### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set I

Including:

- pre-dilator (14 CH)
- puncture cannula (14G)
- dilator (hydrophilic coating)
- guiding catheter with safety lock
- guide wire with dispenser
- gauze compresses
  - syringe
  - scalpel

and

### OPTIMA PERCUTRACH<sup>®</sup> Basic Cuff

#### with atraumatic inserter

Including:

- outer cannula with cuff and 15 mm universal connector
- atraumatic inserter
- 1 transparent, unfenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula

PU = 1 set sterile packaged

- obturator, perforated
- neck strap
- lubricant gel

Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE NUMBER PDT Set	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112424	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112425	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112426	
OD =	INNER DIAN Outer diai Packaging	METER		INNER CANNUL Outer Cannui			

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#### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set I

Including:

- pre-dilator (14 CH)
- puncture cannula (14G) •
- dilator (hydrophilic coating) •
- guiding catheter with safety lock •
- guide wire with dispenser
- gauze compresses
  - syringe
  - scalpel

and

### OPTIMA PERCUTRACH<sup>®</sup> Voice Cuff

#### with atraumatic inserter

#### Including:

fenestrated outer cannula with cuff and • 15 mm universal connector

PU = 1 set sterile packaged

- atraumatic inserter
- 1 red, fenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula
- obturator, perforated
- decannulation cap
- speaking valve
- neck strap
- lubricant gel

Size	ID <sub>ic</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE NUMBER PDT SET	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112434	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112435	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112436	
	INNER DIAM			INNER CANNUL			

.







### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set I

Including:

- pre-dilator (14 CH)
- puncture cannula (14G)
- dilator (hydrophilic coating)
- guiding catheter with safety lock
- guide wire with dispenser
- gauze compresses
- syringe
- scalpel

and

### OPTIMA PERCUTRACH<sup>®</sup> Suction with atraumatic inserter

#### Including:

- outer cannula with cuff, subglottic suction • function and 15 mm universal connector
- atraumatic inserter
- 1 transparent, unfenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner
- obturator, perforated
- funnel connector neck strap lubricant gel

PU = 1 set sterile packaged

Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE NUMBER PDT Set	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112454	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112455	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112456	
OD = 0	INNER DIA <i>n</i> Outer dian Packaging	<b>1ETER</b>		INNER CANNUL Outer Cannul			

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### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set I

#### Including:

- pre-dilator (14 CH)
- puncture cannula (14G) •
- dilator (hydrophilic coating) 0
- guiding catheter with safety lock 0
- guide wire with dispenser
- gauze compresses
  - syringe
  - scalpel

#### and

### OPTIMA PERCUTRACH<sup>®</sup> Suction Voice

#### with atraumatic inserter

#### Including:

- fenestrated outer cannula with cuff, subglottic suction function and 15 mm universal connector
- atraumatic inserter
- 1 red, fenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula

PU = 1 set sterile packaged

- obturator, perforated
- funnel connector decannulation cap
- speaking valve C
- neck strap
- lubricant gel

	Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	Article number PDT Set	
I	7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112444	
	8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112445	
I	9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112446	
		INNER DIAM Outer diam			INNER CANNUL Outer Cannul			

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PU = PACKAGING UNIT

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### PDT Set Type 2







# DILATATION TRACHEOSTOMY DEVELOPED BY GRIGGS

The percutaneous dilatation tracheostomy technique according to Griggs is a minimalinvasive treatment as well. This method implies the tracheal dilation by a tracheal dilating forceps. The closed forceps, featuring a longitudinal duct, is pushed into the trachea via a guide wire. Then the forceps is spread and thus dilates the trachea until the insertion of the required tracheostomy tube is possible.

This technique is a quick and efficient, tissue-conserving dilation procedure and, similar to the Ciaglia method, is characterized by a small skin incision and causing few complications.

The procedure is performed under bronchoscopic control.



Position patient with hyperextension of neck, cover area around the neck with sterile dressing, disinfect skin



Palpation of neck, sonography (recommended), diaphanoscopy of neck area (obligatory), horizontal incision(1,5-2,0 cm) and blunt preparation up to trachea

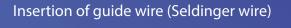


Puncture of trachea









Opening of injection canal by pre-dilator



Insert closed tracheal dilating forceps via guide wire and dilate pre-tracheal tissue first.



Insert forceps further into trachea and dilate tracheal tissue by spreading.

Remove spread forceps.



Moisten tip of atraumatic inserter with lubricant and insert in tracheal orifice via guide wire together with tested tracheostomy tube. Remove atraumatic inserter and guide wire simultaneously.



### PercuTrach® PDT Set Type 2



### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set II

Including:

- tracheal dilating forceps
- pre-dilator (14 CH)
- puncture cannula (14G)
- gauze compresses
- syringe
- scalpel
- guide wire with dispenser

and

### OPTIMA PERCUTRACH<sup>®</sup> Basic Cuff

### with atraumatic inserter

### Including:

- outer cannula with cuff and 15 mm universal connector
- atraumatic inserter
- 1 transparent, unfenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula
- obturator, perforated
- neck strap
- Iubricant gel

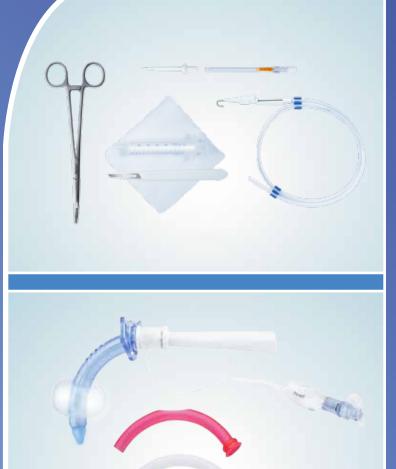
PU = 1 set sterile packaged

Siz	ZE	ID <sub>ic</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE NUMBER PDT Set	
7	7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112324	
8	3	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112325	
9	)	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112326	
<u> </u>	)D = 0	INNER DIAN Outer dian Packaging	METER		INNER CANNUL Outer Cannui			



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### PERCUTRACH® PDT SET TYPE 2



### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set II

### Including:

- tracheal dilating forceps
- pre-dilator (14 CH) •
- puncture cannula (14G)
- gauze compresses
- syringe •
- scalpel •
- guide wire with dispenser •

### and

### OPTIMA PERCUTRACH<sup>®</sup> Voice Cuff

### with atraumatic inserter

### Including:

fenestrated outer cannula with cuff and • 15 mm universal connector

PU = 1 set sterile packaged

- atraumatic inserter
- 1 red, fenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula
- obturator, perforated decannulation cap
- speaking valve •
- neck strap
- lubricant gel •

Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length Along centre Line (OC)	Length Along outer bend (OC)	Article number PDT Set	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112334	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112335	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112336	
OD =	INNER DIAN Outer dian Packaging	AETER		INNER CANNUL Outer Cannui			

**PERCUTRACH<sup>®</sup>** PDT SET TYPE 2

### PERCUTRACH® PDT SET TYPE 2



### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set II

Including:

- tracheal dilating forceps
- pre-dilator (14 CH) •
- puncture cannula (14G)
- gauze compresses
- syringe
- scalpel
- guide wire with dispenser

#### and

### OPTIMA PERCUTRACH<sup>®</sup> Suction

### with atraumatic inserter

#### Including:

- outer cannula with cuff, subglottic suction function and 15 mm universal connector
- atraumatic inserter
- 1 transparent, unfenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula

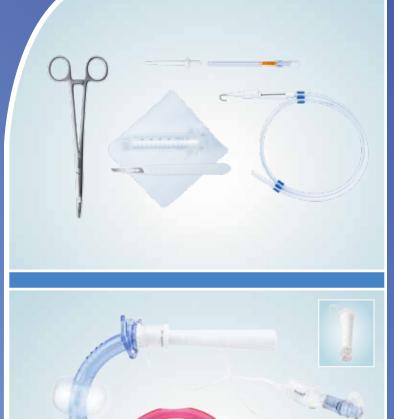
PU = 1 set sterile packaged

- obturator, perforated funnel connector
- neck strap
- lubricant gel

Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length Along centre Line (OC)	Length Along outer bend (OC)	ARTICLE NUMBER PDT Set	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112354	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112355	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112356	
OD =	INNER DIAN Outer diai Packaging	METER		INNER CANNUL Outer Cannui			

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### PercuTrach® PDT Set Type 2



### Package contents per set:

### PERCUTRACH<sup>®</sup> Dilation set II

Including:

- tracheal dilating forceps
- pre-dilator (14 CH)
- puncture cannula (14G)
- gauze compresses
- syringe
- scalpel
- guide wire with dispenser

#### and

#### OPTIMA PERCUTRACH<sup>®</sup> Suction Voice

#### with atraumatic inserter

#### Including:

- fenestrated outer cannula with cuff, subglottic suction function and 15 mm universal connector
- atraumatic inserter
- 1 red, fenestrated inner cannula
- 1 white, unfenestrated, radiopaque inner cannula

PU = 1 set sterile packaged

- obturator, perforated
- funnel connector
- decannulation cap
- speaking valve
- neck strap
- lubricant gel

Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length Along centre Line (OC)	Length Along outer bend (OC)	Article number PDT Set	
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	112344	
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	112345	
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	112346	
OD = 0	INNER DIAM Outer diam Packaging	AETER		INNER CANNUL Outer Cannul			



SET COMPONENTS

The different components of the **PDT Sets** are also available separately and can be combined individually.



Dilation Set I (according to the method developed by Ciaglia)



Dilation Set II (according to the method developed by Griggs)



Optima PercuTrach<sup>®</sup> with atraumatic inserter



**DILATION SETS** 

### DILATION SETS

# Primed Percutrach

#### DILATATIONSSET 1

	DILATION SET 1	
	KIT DE DILATATION I	

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### DILATION SET I





### DILATION SET II

### DILATION SET II



### Including:

- tracheal dilating forceps
- pre-dilator (14 CH)
- puncture cannula (14G)
- gauze compresses
- syringe
- scalpel
- guide wire with dispenser

PU = 1 set sterile packaged

102087

ARTICLE NUMBER

PU = PACKAGING UNIT

## **OPTIMA PERCUTRACH®**



OPTIMA PERCUTRACH®

### WITH ATRAUMATIC INSERTER

	Optima PercuTrach®									
		1				out uni atra 1 tr 1 w car obt nec	IMA PERCUTRACH Basic Cuff with atraumatic inserter ing: ter cannula with cuff and 15 mm versal connector aumatic inserter ansparent, unfenestrated inner cannula white, unfenestrated, radiopaque inner inula curator, perforated ck strap ricant gel			
Size	ID <sub>ic</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length alon outer bend (C		ARTICLE NUMBER			
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm		102424			
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm		102425			
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm		102426			
						fen 15 i atra 1 re 1 w inn obt dec spe nec lub	estrated outer cannula with cuff and mm universal connector aumatic inserter ed, fenestrated inner cannula white, unfenestrated, radiopaque ther cannula curator, perforated cannulation cap taking valve ck strap ricant gel			
Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length Along centre Line (OC)	Length alon Outer bend ((		ARTICLE NUMBER			
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm		102434			
8 9	6,4 mm 7,4 mm	8,0 mm 9,0 mm	11,6 mm 12,6 mm	75,5 mm 81,0 mm	87,0 mm 93,0 mm		102435 102436			
ID = I OD = (	NNER DIAM DUTER DIAM PACKAGING	NETER Meter	IC =	INNER CANNULA Outer Cannula						

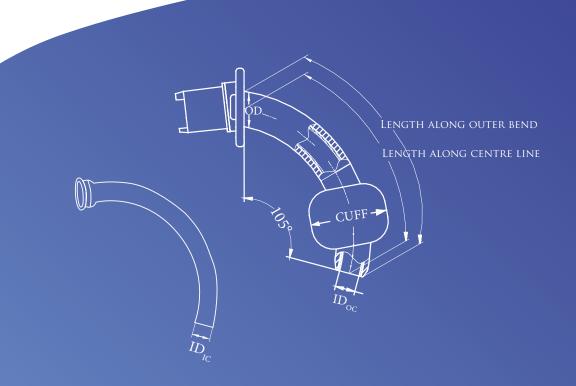
OPTIMA PERCUTRACH®

### WITH ATRAUMATIC INSERTER

Optima PercuTrach®								
					Inclue Inclue	TIMA PERCUTRACH Suction with atraumatic inserter dding: uter cannula with cuff, subglottic suction unction and 15 mm universal connector traumatic inserter transparent, unfenestrated inner cannula white, unfenestrated, radiopaque inner annula bturator, perforated unnel connector eck strap ibricant gel		
Size	ID <sub>IC</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE NUMBER		
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	102454		
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	102455		
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	102456		
					Inclu In	TIMA PERCUTRACH <sup>®</sup> Suction Voice with atraumatic inserter ding: enestrated outer cannula with cuff, ubglottic suction function and 15 mm niversal connector traumatic inserter red, fenestrated inner cannula white, unfenestrated, radiopaque inner annula bturator, perforated unnel connector ecannulation cap beaking valve eck strap ubricant gel		
Size	I D <sub>ic</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along outer bend (OC)	ARTICLE ) NUMBER		
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm	102444		
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm	102445		
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm	102446		
OD = OI	INER DIAM Uter Diam Ackaging I	ETER		NNER CANNULA Duter Cannula				

	Accessories					
	А			OPTIMA PERCUTRAC single inner cannula Inner cannulas are available in riants:	IS	
	B C			<ul> <li>transparent, unfenestrate</li> <li>red, fenestrated</li> <li>white, unfenestrated, radi</li> <li>PU = 5 piec sterile pack</li> </ul>	opaque	
Size	ID	Transparent, unfenestrated (A)	RED, Fenestrated (B)	WHITE, UNFENESTRATED, Radiopaque (C)	PU	
7	5,4 mm	102019	102029	102039	5/ Box	
8	6,4 mm	102020	102030	102040	5/Box	
9	7,4 mm	102021	102031	102041	5/Box	
			Guide wire with dispenser (Seldinger wire) • made of kink-resistant NiTiNOL • individually sterile packaged PU = 5 pieces sterile packaged			
			ARTICLE NUMBER			
	INER DIAMET				-	
PU = PA		N11				





### MEASUREMENT CHART FOR OPTIMA PERCUTRACH°:

FOR THE TYPES BASIC CUFF, VOICE CUFF, SUCTION AND SUCTION VOICE

Size	I D <sub>ic</sub>	ID <sub>oc</sub>	OD	Length along centre line (OC)	Length along Outer bend (OC)
7	5,4 mm	7,0 mm	10,5 mm	70,0 mm	79,0 mm
8	6,4 mm	8,0 mm	11,6 mm	75,5 mm	87,0 mm
9	7,4 mm	9,0 mm	12,6 mm	81,0 mm	93,0 mm

 $ID_{IC}$  = INNER DIAMETER OF INNER CANNULA AT BOTTOM OF TUBE

 $\mathrm{ID}_\mathrm{OC}$  = inner diameter of outer cannula at bottom of tube

OD = OUTER DIAMETER OF OUTER CANNULA BEHIND THE FLANGE

IC = INNER CANNULA

OC = OUTER CANNULA

### MANUFACTURER

Primed<sup>®</sup>HALBERSTADT MEDIZINTECHNIK GMBH STRASSE DES 20. JULI 1 D-38820 HALBERSTADT PHONE.: 0049-(0)3941-668-6 FAX: 0049-(0)3941-24565 PRIMED@PRIMED-HALBERSTADT.DE

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