Instruction For Use – TempoCaps - EGFR Marker

In Vitro Diagnostic Medical Device

NEAR PATIENT TESTING

AVERTISSEMENT
LES MESURES DOIVENT ÊTRE EFFECTUÉES EXCLUSIVEMENT SUR DES TISSUS EX VIVO.

Intended Use

The TempoCaps is an In Vitro Diagnostic device of the reagent type, used in combination with the TempoTouch (see User Manual TempoTouch REG-REC-022-A) to identify and qualitative measure the over- or under-expression of membrane EGFR on the surface of a tissue during the surgical excision of head and neck carcinomas. It is used in the operating room by healthcare professionals (operating room nurse and surgeon).

Function

- To attach to the end of the TempoProbe, providing it with the ability to detect EGFR
- To detect the presence of EGFR antigen
- To emit a variable light signal depending on the presence of EGFR, in response to the laser emitted by the TempoTouch
- To take a reference on healthy or tumorous tissue / To allow the measurement of relative expression levels compared to a reference tissue

Using this technology should reduce the need for frozen section examination, thereby reducing the duration of the surgery. In case of uncertainty, the surgeon always has the option to perform frozen sections examination with the pathology department.

The device is not intended perform a diagnostic or to replace the final intraoperative analysis of the tumour performed by the anatomopathological department.

Type of tissue analyzed and counter indications

TempoCaps can be used to identify any significant over/under expression of a surface antigen characteristic of a pathological state on the surface of a tissue, compared with a reference. In this case, the antigen is EGFR.

In some cases, use of the device is counter-indicated:

- History of treatment with cetuximab or other anti-EGFR monoclonal antibodies
- Lack of EGFR expression by tumour cells previously demonstrated on biopsy
- The area to be tested was burned using an electric scalpel, laser or other device used during surgery.

Inability to identify with a reasonable degree of confidence an area of healthy tissue or tumour that can be used as a reference.

Note : The device cannot be used on areas that have been burned, for example by an electric scalpel or laser. This applies both to the reference measurement and to subsequent measurements.

TempoCaps technical caracteristic

Tumour Marker	EGFR
Type of device	Do not reuse
TimeLife	6 touch
Shelf life	9 weeks
Storage and transport conditions	keep between +2°C à +8°C

Storage and stability

TempoCaps must remain moist throughout their lifetime.

They are packed in HEPES-NaCl to preserve their hydration.

TempoCaps have a shelf-life of 9 weeks in the refrigerator at 2°C to 8°C. When used at room temperature, TempoCaps should be hydrated in saline after 5 minutes, and changed after 15 minutes of use.

Solution HEPES-NaCl

Ingredient	Concentration
HEPES (CAS 7365-45-9)	10 mM
NaCl (CAS 7647-14-5)	150 mM

Packaging

Each TempoCaps is individually packaged in disposable tubes filled with HEPES/NaCl solution. Individually wrapped capsules are packaged in heat-sealed bags.

Quality Control

The TempoTouch evaluates the performance of each new TempoCaps mounted on a TempoProbe. If a capsule is faulty, the TempoTouch will detect it and display a specific error message. If a TempoCaps remains unused for 5 minutes, TempoTouch will display a message telling you to soak it in a solution. After 15 minutes, the TempoTouch will display a message telling you to change the TempoCaps.

Target population

Patient profile : Men and women aged over 18 with squamous cell carcinoma of the head and neck requiring curative surgery.

User profile : Surgeon

Operating environment

Operating room (outside sterile fields)

Precautions for use

----------**WARNING** ----------

- Respect best-before date
- Respect storage temperatures
- Do not reuse a capsule that has already been used
- Do not use a dropped capsule
- Do not expose capsule to natural light
- Do not use the capsules if the heat-sealed sachet is damaged.
- Remove the capsules from the storage fridge as late as possible.
- The device must be operated by a qualified operator (hospital staff, doctor).
- The device must not come into contact with the patient.
- No modifications to the device are authorized.
- Only use accessories supplied by Dyameo.
- The device must only be used with Dyameo's devices.
- The device is not intended for use in the sterile field of the operating room.
- Check the integrity of the device case, power cable, optical fibre, footswitch and cable before each use.
- Do not place the appliance near a source of heat.

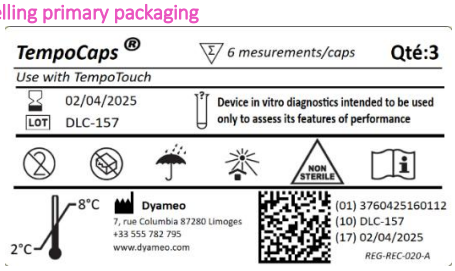
Residual risk

No residual risk identified

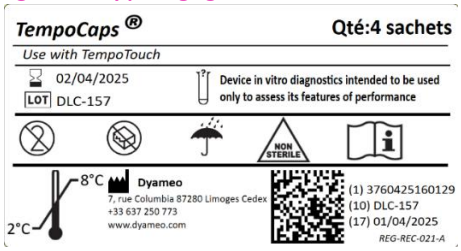
Logos et pictograms

Σ	Sufficient content for « n » trials		Humidity sensitive
	Shelf life		Storage away from sunlight
LOT	Batch	NON STERILE	Non-sterile
	DIV performance evaluation system		Consult the instructions for use
	Do not reuse		Temperature limit
	Do not use if packaging is damaged		Manufacturer

Labbelling primary packaging



Labelling secondary packaging



Using TempoCaps

Installation of TempoCaps

This procedure is described in detail in the TempoTouch user manual.

- Remove the cap from the TempoProbe. Be careful not to touch the end of the TempoProbe.
- Check that the stainless-steel ferrule is clean and free of marks.
- Pierce the lid containing the capsule with the probe. Insert the end of the fibre into the capsule until it clips into place.
- Remove the fibre with the plug.
- During this step, you can also remove the probe without the cap. In this case, make sure that the capsule is still correctly attached to the end of the TempoProbe after passing through the cap.
- The probe is ready for the performance verification stage.
- During this step, you can also remove the probe without the blue plug. In this case, make sure that the capsule is still correctly attached to the end of the TempoProbe after passing through the blue plug.
- The probe is ready for the performance verification step.

TempoCaps verification phase

- This stage checks the conformity of the capsule. It must be performed away from ambient light to ensure accurate collection of the emitted light signal. Place the end of the probe and the capsule in the black compartment of the unit
- Close the trapdoor and press the TempoTouch footswitch to initiate the verification

Reference measurement

To make a comparison between healthy and tumour tissue, the device needs a reference measurement. According to the surgeon's choice and the surgical specimen, this reference measurement must be taken either:

- on tissue that has been visually identified as clearly healthy. This tissue must be similar to that in which the tumour developed. This is referred to as a 'Healthy' reference.
- on tissue that has been visually identified as clearly tumoral, budding and non-necrotic. This is referred to as 'TUMORAL' reference.

Note: *The device must not be used if it is impossible to identify with a reasonable degree of certainty a healthy or tumoral area that can be used as a reference.*

- Use the left and right navigation keys to select the type of tissue you want to use as reference - HEALTHY' or 'TUMORAL' - and press 'ENTER'.
- The device displays a screen so you can double-check the choice you have previously made
- Position the probe on the tissue to be analysed, keeping it as perpendicular as possible to the plane of the tissue.
- Hold the probe in place for about 5 seconds.
- Press the footswitch to start a measurement.
- While the measurement is being captured:
  - The red light under the 'laser' logo is illuminated.
  - An audible signal is also emitted.
  - The display indicates a measurement in progress.
- Hold the probe still on the tissue and keep the footswitch pressed until the sound of the buzzer stops.
- Once the measurement is complete, press the 'ENTER' button to save the reference measurement.
- If the measurement is invalid (if the probe has been moved during the measurement, or if the surgeon identify afterward a more representative area of healthy or tumour tissue usable as reference), press 'BACK' and repeat the reference measurement as described above.
- Each reference performed decreases the number of possible future measurements with the same capsule.

Taking measurements

Tissu measurement

- Once the capsule has been checked and the reference measurement taken, the surgeon can proceed with the analysis of the explanted tissue.
- Place the probe in contact with the tissue you intend to analyse, in the same way as for the reference sample.
- Start the measurement by pressing the footswitch until the end of the acoustic signal.

Display of results

3 levels of results are possible:

- $EGFR_{low}$: The tissue is considered healthy
- $EGFR_{intermediate}$: The tissue cannot be analysed with precision. The surgeon follows the usual operating procedure (frozen section analysis, etc.).
- $EGFR_{high}$ The tissue is considered to have a high level of EGFR.

For each analysis, the results are reported in the history in order of analysis. The last measurement is displayed on the main part of the screen.

To start a new measurement, reposition the probe on the tissue to be analysed and press the footswitch.

When the capsules have reached their maximum number of analysis, a message appears prompting you to change capsules.

Replacing the capsule

After 5 analyses (or less if several reference measurements have been carried out), the capsule must be changed.

Remove the capsule from the TempoProbe using a pair of pliers or tweezer. Be sure to position it on the top of the capsule (towards the porthole) when removing it to avoid damaging the optical fiber.

Press the 'CAPSULE' button to start the replacement procedure. Follow the procedure described in §7.4.2 of the TempoTouch IFU.

Elimination

The capsules are for single use only and must be treated after use as infectious risk waste (IRW) in accordance with operating theatre practices.

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