# High-energy devices and standard monopolar/bipolar devices: an HTA in the Italian surgical setting

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HTA178

## Background

In the last 30 years, surgeons have become progressively persuaded by the usefulness of the so-called "**High-energy devices" (HEDs) in surgical practices, as alternative medical devices to standard monopolar or bipolar devices**

Despite the growing interest in such devices, today **the choice to use HEDs or traditional monopolar or bipolar devices is mainly based on the surgeon's preferences**

Given the lack of a standardized use of HEDs in the Italian clinical practice, **the deep investigation of the impacts of their higher implementation in surgery is strictly required**

## Objective

To define the **incremental benefits concerning the routinely implementation of HEDs with respect to standard monopolar/bipolar ones**, assuming the hospital perspective, within different surgical settings: appendectomy, hepatic resections, colorectal resections, cholecystectomy, splenectomy, hemorrhoidectomy, thyroidectomy, esophago-gastrectomy, breast surgery, adrenalectomy, and pancreatectomy

## Methods

A **Health Technology Assessment** was conducted in 2021 in Italy

The nine EUnetHTA Core Model dimensions were deployed considering:

- **literature evidence**, to define efficacy and efficiency indicators, and the target population potentially eligible to HEDs or standard devices
- **quantitative health economics tool**s useful for the clinical pathway economic evaluation, the budget impact analysis, and the definition of the organizational and accessibility advantages, in terms of time/procedures savings
- administration of **qualitative questionnaires** to 23 healthcare professionals based on a 7-item Likert scale, ranging from -3 to +3

## Conclusions

The introduction of HEDs could lower the overall process costs, by **freeing up economical and organizational resources for the hospitals**, thus representing a sustainable choice of **improvement and optimization of resources**

This can potentially **reduce the waiting lists**, thus **improving the overall accessibility to care**

Relevant advantages emerged in considering the patients' and the society point of view, in terms of **reduction of productivity losses due to hospital stay**, with important **out-of-pocket expenditure savings** ranging from a minimum of 4.74% to a maximum of 10.71%

In conclusion the **routine use of HEDs can be considered proper and sustainable**, in a balance between costs and outcomes, thus improving surgical outcomes and guarantying, at the same time, cost savings and patients' satisfaction

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DIMENSIONS OF THE HTA ASSESSMENT

### *Results from literature evidence*

Literature declared an overall average decrease in operating time and length of stay, using HEDs, in most surgical settings

| Rate of surgeries within the eleven setting under assessment | Case-mix derived from the Italian "SDO Report" (2019) |
|---|---|
| Appendectomy | 8% |
| Breast surgery | 9% |
| Thyroidectomy/parathyroidectomy | 18% |
| Adrealectomy | 3% |
| Pancreasectomy | 13% |
| Liver resections | 6% |
| Cholecystectomy | 27% |
| Colorectal surgery | 5% |
| Esophago-gastric surgery | 5% |
| Haemorrhoidectomy | 5% |
| Splenectomy | 1% |

### *Results from quantitative health economics tools*

| Surgical Settings | Monopolar/Bipolar Device | HEDs | Difference (%) |
|---|---|---|---|
| Appendectomy | 4,822.94 € | 4,969.70 € | 3.04% |
| Breast surgery | 4,194.84 € | 3,941.20 € | -6.05% |
| Thyroidectomy/parathyroidectomy | 3,285.04 € | 3,296.27 € | 0.34% |
| Adrealectomy | 3,792.12 € | 3,715.12 € | -2.03% |
| Pancreasectomy | 9,731.81 € | 8,385.03 € | -13.84% |
| Liver resections | 6,370.83 € | 6,123.94 € | -3.88% |
| Cholecystectomy | 3,309.96 € | 3,392.71 € | 2.50% |
| Colorectal surgery | 4,516.50 € | 4,722.92 € | 4.57% |
| Esophago-gastric surgery | 5,712.27 € | 5,910.78 € | 3.48% |
| Haemorrhoidectomy | 2,766.81 € | 2,694.49 € | -2.61% |
| Splenectomy | 4,957.59 € | 4,595.36 € | -7.31% |
| **Weighted total costs, considering the case-mix derived from the Italian "SDO report" (2019)** | **4,676.11 €** | **4,529.13 €** | **-3.14%** |

HEDs would lead to an **overall economic saving** for the conduction of 178,619 surgeries, as well as would generate significant **organizational savings**, in terms of release both in operating room time and in hospitalization days

| Budget Impact Analysis | Case-mix derived from the Italian "SDO Report" (2019) |
|---|---|
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 1 (current HEDs implementation) | -3.52% |
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 2 (considering a 100% replacement rate) | -3.27% |

| Organizational impact concerning the release in operating room time | Case-mix derived from the Italian "SDO Report" (2019) |
|---|---|
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 1 (current HEDs implementation) | -4.19% |
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 2 (considering a 100% replacement rate) | -9.02% |
| **Organizational impact concerning the release in hospitalization days** | **Case-mix derived from the Italian "SDO Report" (2019)** |
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 1 (current HEDs implementation) | -15.71% |
| AS IS Scenario (no HEDs implementation) versus Innovative Scenario 2 (considering a 100% replacement rate) | -30.73% |

### *Results from the qualitative assessment*

| | Monopolar/bipolar devices - "AS IS" Scenario | HEDs - "TO BE" Scenario | P-value |
|---|---|---|---|
| **Effectiveness** | **-0.10** | **1.19** | **0.004** |
| **Safety** | **0.22** | **1.10** | **0.022** |
| Equity Impact | 0.41 | 0.55 | 0.146 |
| **Social and Ethical Impact** | **0.20** | **0.70** | **0.048** |
| Legal Impact | 0.95 | 0.84 | 0.315 |
| Organizational Impact - 12 months | 0.13 | 0.20 | 0.068 |
| **Organizational Impact - 36 months** | **0.18** | **0.53** | **0.053** |

- Based on a 7-item Likert scale, healthcare professionals' perceptions confirmed the superiority of HEDs with respect to standard devices, declaring a **better safety** (1.10 vs 0.22, p-value=0.022) and **effectiveness profile** (1.19 vs -0.10, p-value=0.004)
- They declared the potentialities of HED to **improve patients' quality of life** (1.09 vs 0.22, p-value=0.002) **and satisfaction** (1.17 vs 0.35, p-value=0.005), as well as their capability to **optimize both the patients' post-operative recovery** (1.22 vs 0.26, p-value=0.001) **and pain** (1.04 vs 0.09, p-value=0.001)